REMARKS

Reconsideration of the allowability of the present application is requested respectfully.

Status of the Claims

Claims 1 to 6 were acted upon by the Examiner in the Office Action dated July 5, 2005. Claims 7 to 11 were withdrawn. Claims 2, 4, and 6 have been amended. Claims 1, 3, and 5 have been cancelled. Claims 12 to 30 have been added. Accordingly, Claims 2, 4, 6, and 12 to 30 are presented for examination.

Support for newly presented Claim 12 and 13 can be found throughout the application, particularly on page 13, line 1 to page 14, line 17. Support for newly presented Claim 16 can be found throughout the application, particularly on page 10, lines 3 to 6. Support for newly presented Claims 17 and 18 can be found throughout the application, particularly on page 5, lines 11 to 19. Support for newly presented Claims 14, 15, and 19 to 22 can be found throughout the application, particularly on page 27, line 12, to page 29, line 2, and page 42, line 8, to page 44, line 11. Support for newly presented Claims 23 to 30 can be found throughout the application, particularly on pages 17, line 17, to page 18, line 3.

Affirmation of Sequence Election

Applicants affirm the election of SEQ ID NO: 24.

Arguments

In response to the Examiner's Office Action, dated July 5, 2005, Applicants respectfully traverse the Examiner's rejection of Claims 2, 4, and 6.

Summary of the Invention

Applicants have identified membrane translocating peptide (MTLP) sequences, along with fragments, motifs, derivatives, analogs and peptidomimetics thereof that enhance the cellular uptake of pharmaceutically active agents. Multiple MTLP sequences are disclosed. The MTLPs may comprise L- or D-form amino acids, including retroinverted peptides, or molecular

analogs of amino acids, and may also be linear or cyclic molecules. The MTLPs may be generated by expression of a polynucleotide encoding the MTLP or by chemical synthesis. Prior to applicants' invention, the presently claimed MTLP sequences had not been disclosed. Furthermore, particles comprising MTLPs that enhance uptake of an agent had not been previously described. Thus, applicants have advanced the state of the art by providing for the first time the means which enable those in the field to increase the uptake of pharmaceutically active agents.

Applicants have further advanced the state of the art by providing means for generating MTLP/particle complexes that enhance the uptake of pharmaceutically active agents. Such MTLP/particle complexes include, but are not limited to, particles such as a microparticle, a nanoparticle, or a liposome. Use of such an MTLP/particle complex to transfer polynucleotides into a cell results in a higher expression of the gene encoded by the polynucleotide as compared to particles lacking MTLPs.

While not wishing to be bound by a theory respecting the reason for the effectiveness of applicants' development, applicants believe that the MTLP helps improve the interaction of an agent or particle with a cell membrane thus increasing the efficiency of transfer of the agent across the cell membrane.

The §112, First Paragraph, Rejections

The Examiner has rejected Claims 1 to 6 under 35 U.S.C. §112, first paragraph (written description). The Examiner has asserted that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors were in possession of the claimed invention at the time of filing.

In particular, the Examiner has asserted that the specification does not teach all derivatives, fragments, motifs, analogs, or peptidomimetics of SEQ ID NO: 24.

Applicants have amended Claim 2 to remove reference to "a derivative, fragment, motif, analog or peptidomimetic thereof (MTLP)" of the peptides. Claims 1, 3, and 5 have been cancelled. Thus, this amendment should obviate the Examiner's rejection under 35 U.S.C. §112, first paragraph in this regard.

In addition, claims 3 to 6 have been rejected as the Examiner has asserted that the structure or function of an active agent or active particle is not disclosed in a complex with an MTLP, therefore the claims do not satisfy the written description requirement.

Applicants respectfully traverse this assertion.

Page 12, lines 6 to 21, of the application includes definitions of "active agent", "active particle", "complexed to". Page 12, lines 16 to 17, recites "'Complexed to', as used herein, includes adsorption, non-covalent coupling and covalent coupling of a MTLP to an active agent or to an active particle". Accordingly, the structure of an active agent/particle complexed to an MTLP includes a non-covalent or covalent linkage of active agent/particle to the MTLP. Example 9 (page 41, line 10, to page 42, line 7) describes how an MTLP is complexed with a liposome (an active particle) and DNA (an active agent). Accordingly, it is clear that applicants have disclosed an active agent and an active particle complexed with an MTLP and thus were in possession of such a complex.

The Examiner has also rejected Claims 1 and 2 as they refer to "an amino acid sequence substantially as set forth SEQ ID NO: ...". The Examiner has asserted that the inventors have not demonstrated possession of a sequence substantially identical to any of the claimed SEQ ID NOs.

Applicants have cancelled claim 1 and amended clam 2 to not recite "substantially". Thus, this amendment should obviate the Examiner's rejection under 35 U.S.C. §112, first paragraph in this regard.

In view of the above, Applicants respectfully request the withdrawal of the rejections to Claims 2, 4, and 6 under 35 U.S.C. §112, first paragraph.

The §112, Second Paragraph, Rejections

The Examiner has rejected Claims 1 to 6 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In particular, the Examiner has found the terms "substantially", "motif", and "peptidomimetic" of claims 1 and 2 to be indefinite.

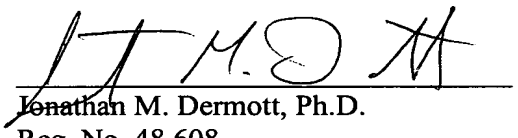
Applicants have cancelled claim 1 and amended clam 2 to not recite "substantially", "motif", or "peptidomimetic". Thus, this amendment should obviate the Examiner's rejection under 35 U.S.C. §112, second paragraph in this regard.

The §102 Rejections

The Examiner has rejected claim 1 under 35 U.S.C. §102(e) as being anticipated by Lin et al. Claim 1 has been cancelled.

The Examiner has rejected claim 2 under 35 U.S.C. §102(e) as being anticipated by Nadler et al. The Examiner has asserted that Nadler et al. discloses a peptide sequence substantially similar to SEQ ID NO: 24. Applicants have amended clam 2 to not recite "substantially". Thus, this amendment should obviate the Examiner's rejection under 35 U.S.C. §102(e) in this regard. Accordingly, applicants respectfully request the withdraw of the rejection to claim 2 under 35 U.S.C. §102(e) in view of Nadler et al.

Respectfully submitted,



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